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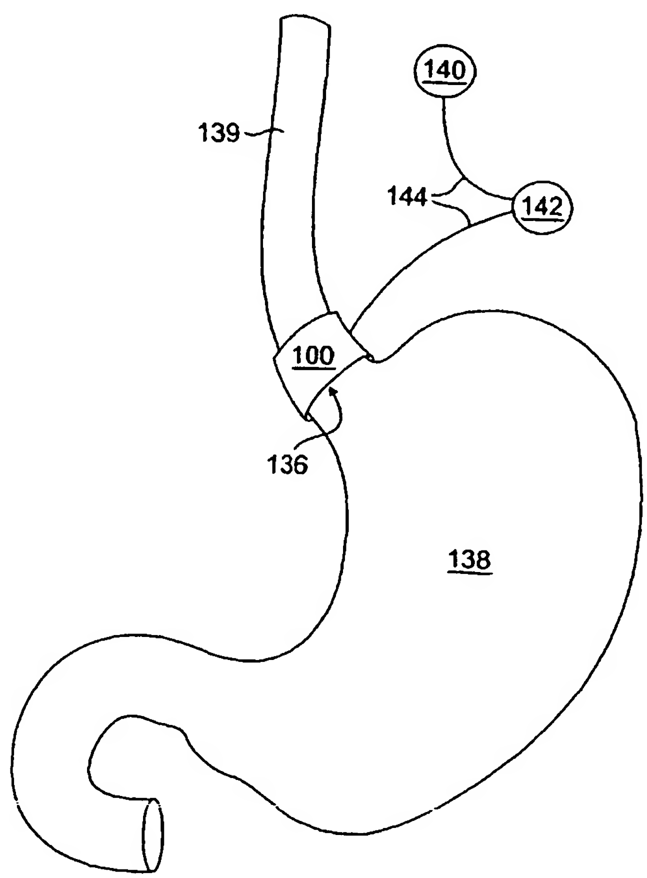
(54) Title: ELECTROACTIVE POLYMER BASED ARTIFICIAL SPHINCTERS AND ARTIFICIAL MUSCLE PATCHES




(57) Abstract: Provided are artificial muscle patches, which are adapted to be implanted adjacent a patient's heart, and artificial sphincter cuffs, which are adapted to be implanted around a body lumen, such as the urethra, the anal canal, or the lower esophagus. The devices of the present invention comprise: (a) one or more electroactive polymer actuators; and (b) a control unit for electrically controlling the one or more electroactive polymer actuators to expand or contract the devices.

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# ELECTROACTIVE POLYMER BASED ARTIFICIAL SPHINCTERS AND ARTIFICIAL MUSCLE PATCHES

## FIELD OF THE INVENTION

[0001] The present invention relates to medical devices, and more particularly to artificial sphincters and artificial muscle patches that are based on electroactive polymers.

## BACKGROUND OF THE INVENTION

[0002] Millions of Americans are incontinent. Incontinence is the second most common reason for institutionalization of the elderly, generating costs of several billion dollars per year. Incontinence commonly arises from malfunction of the urethral sphincter. The urethral sphincter is an external sphincter formed about the urethra in both males and females which, when functioning normally, constricts the urethra and prevents flow of urine from the bladder, except when the bladder is voided during normal urination. Unfortunately, a spectrum of medical conditions can result in improper functioning of the urethral sphincter and lead to incontinence, including surgical injury following transurethral resection or radical prostatectomy, neurologic injury, or direct injury to the sphincter itself.

[0003] There are numerous prior art prosthetic sphincters for selectively closing and opening the urethra to prevent incontinence. These devices typically incorporate an inflatable cuff which surrounds the urethra, and which is inflated to restrict urine flow in the urethra. Examples of such prosthetic sphincters are seen in U.S. Patent Nos. 4,222,377, and 5,562,598. These patents describe devices having an inflatable urethral cuff, a balloon reservoir/pressure source, and a pump. The cuff is typically implanted around the bladder neck in women, and around the bulbous urethra in most men. The implanted cuff functions similarly to a blood pressure cuff.

[0004] Fecal incontinence, like urinary incontinence is a debilitating condition

[0011] Current treatment options for GERD include various endoscopic, laproscopic and pharmaceutically-based therapies, such as fundoplication, RF ballooning, and powerful acid suppressing pharmaceuticals such as Zantac® (ranitidine), Tagamet® (cimetidine) and Pepcid® (famotidine). While these options offer a highly focused therapeutic potential, they fail in providing a long-term cure, and are not conducive to patient comfort.

[0012] As such, the need for a more dynamic and versatile option for the long-term treatment of GERD is apparent. To that end, in another aspect of the present invention, an artificial lower esophageal sphincter is provided, which is based on electroactive polymers that are under electronic control.

[0013] Congestive heart failure is a progressive and debilitating illness. The disease is characterized by a progressive enlargement of the heart. As the heart enlarges, it is required to perform an increasing amount of work in order to pump blood with each heartbeat. In time, the heart becomes so enlarged that it cannot adequately supply blood. An afflicted patient is fatigued, unable to perform even simple exerting tasks, and experiences pain and discomfort.

[0014] Millions of Americans suffer from congestive heart failure, with economic costs of the disease having been estimated at tens of billions of dollars annually.

[0015] Patients suffering from congestive heart failure are commonly grouped into four classes (i.e., Classes I, II, III and IV). In the early stages (e.g., Classes I and II), drug therapy is the most commonly prescribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Unfortunately, there is presently no cure for congestive heart failure. Even with drug therapy, the disease will progress. Further, the drugs may have adverse side effects.

[0016] One treatment for late-stage congestive heart failure is heart transplant. However, even if the patient qualifies for transplant and a heart is available for transplant, it is noted that heart transplant procedures are very risky, invasive, expensive and only shortly extend a patient's life. For example, prior to transplant, a Class IV patient may have a life expectancy of 6 months to one-year. Heart transplant may improve the expectancy to about five years. Similar risks and difficulties exist for mechanical heart transplants as well.

SUMMARY OF THE INVENTION

[0021] According to a first aspect of the invention, an artificial sphincter is provided, which comprises: (a) a cuff that is adapted for placement around a body lumen, which cuff comprises one or more electroactive polymer actuators; and (b) a control unit for electrically controlling the one or more electroactive polymer actuators to expand or contract the cuff.

[0022] The one or more electroactive polymer actuators of the artificial sphincter can beneficially comprise (a) one or more active members, (b) a counter-electrode, and (c) an electrolyte disposed between the active member and the counter-electrode.

[0023] In some preferred embodiments, the active members are disposed upon one or more substrate layers. The active members can be provided in numerous configurations on the substrate layer(s), including nonlinear configurations that are capable of exerting force vectors along at last two axes, for instance, an S-shaped configuration. The substrate layer(s) can be insulating or conductive in nature. Where insulating, it may be preferred to provide conductive lines on the substrate layer(s) to allow electrical communication between active members and the power source.

[0024] In certain embodiments, the cuff will further comprise a barrier layer and/or a mesh layer.

[0025] The action of the artificial sphincter of the present invention can be controlled using a variety of control units, for example, (a) power source and a simple switch or (b) power source and a logic/control device such as a computer.

[0026] In some embodiments, the cuff is provided with a restoring force to bring it into an expanded or a contracted state, preferably by including at least one elastic structural element within the cuff to supply such a restoring force. For example, the artificial sphincter cuff can be provided with an elastic annular tube structure whose length increases upon a decrease in its cross-sectional diameter.

[0027] The artificial sphincters of the present invention can also comprise a sensing system (such as a system comprising strain gauges) for sensing the degree of contraction of the electroactive polymer actuators.

[0028] Opposing ends of the artificial sphincter cuffs of the present invention may be provided with fasteners for securing the cuff around the body lumen.

and (b) a control unit for electrically controlling the one or more electroactive polymer actuators to expand or contract the artificial muscle patch.

[0039] As above, the one or more electroactive polymer actuators of the artificial muscle patch can beneficially comprise (a) one or more active members, (b) a counter-electrode, and (c) an electrolyte disposed between the active member and the counter-electrode. In some preferred embodiments, the active members are disposed upon one or more substrate layers. The active members can be provided in numerous configurations on the substrate layer(s), including nonlinear configurations that are capable of exerting force vectors along at last two axes, for example, an S-shaped configuration. The substrate layer(s) can be insulating or conductive in nature. Where insulating, it may be preferred to provide conductive lines on the substrate layer(s) to allow electrical communication between active members and the power source. In certain embodiments, the patch will also further comprise a barrier layer and/or a mesh layer.

[0040] The action of the artificial muscle patch of the present invention can be controlled using a variety of control units, for example, (a) a power source and a simple switch or (b) power source and a logic/control device such as a computer.

[0041] The artificial muscle patch can further comprise a sensing system for detecting a patient's heartbeat, in which case the control unit preferably paces the contraction and expansion of the electroactive polymer actuators with the heartbeat.

[0042] Alternatively, the control unit can pace both the heart as well as the contraction and expansion of said electroactive polymer actuators.

[0043] Other embodiments are directed to the treatment of congestive heart failure by implanting into a patient an artificial muscle patch in accordance with the present invention.

[0044] One advantage of this aspect of the present invention is that an artificial muscle patch is provided, which is based on electroactive polymers under electronic control.

[0045] Another advantage of this aspect of the present invention is that a device is provided, which can supply cardiac constraint and, if desired, can be electrically paced to improve cardiac performance.

[0046] A further advantage of this aspect of the present invention is that a device

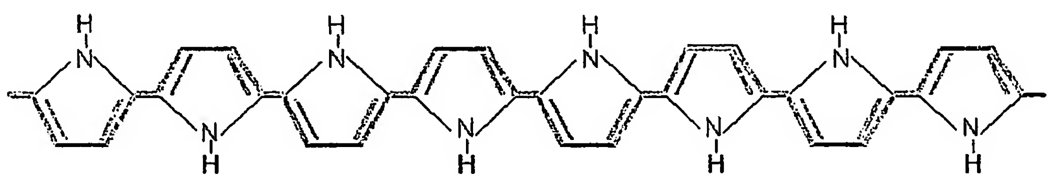
[0057] Fig. 9A is a schematic perspective view illustrating the deployment upon the heart of an artificial muscle patch, in accordance with an embodiment of the invention; and

[0058] Fig. 9B is a schematic cross-sectional view of the artificial muscle patch of Fig. 9A, taken along line A-A'.

DETAILED DESCRIPTION OF THE INVENTION

[0059] The present invention relates to medical devices, such as artificial sphincters and artificial muscle patches, which are operated using electroactive-polymer-based actuators.

[0060] Electroactive polymers, also referred to as "conductive polymers" or "conducting polymers," are characterized by their ability to change shape in response to electrical stimulation. They typically structurally feature a conjugated backbone and have the ability to increase electrical conductivity under oxidation or reduction. Some common electroactive polymers are polyaniline, polypyrrole and polyacetylene. Polypyrrole is pictured below:



[0061] These materials are typically semi-conductors in their pure form. However, upon oxidation or reduction of the polymer, conductivity is increased. The oxidation or reduction leads to a charge imbalance that, in turn, results in a flow of ions into or out of the material in order to balance charge. These ions, or dopants, enter the polymer from an ionically conductive electrolyte medium that is coupled to the polymer surface. If ions are already present in the polymer when it is oxidized or reduced, they may exit the polymer.

[0062] It is well known that dimensional changes may be effectuated in certain conducting polymers by the mass transfer of ions into or out of the polymer. For example, in some conducting polymers, the expansion is due to ion insertion between chains, whereas in others interchain repulsion is the dominant effect. Thus, the mass

configuration (e.g., by selecting appropriate ionic species and/or ionic species concentration). However, other actuators types are clearly appropriate.

[0067] Electrolyte 14 may be a liquid, a gel, or a solid, so long as ion movement is allowed. Moreover, where the electrolyte 14 is a solid, it should move with the active member 12 and should not be subject to delamination. Where the electrolyte 14 is a gel, it may be, for example, an agar or polymethylmethacrylate (PMMA) gel containing a salt dopant. Where the electrolyte is a liquid, it may be, for example, a phosphate buffer solution, potassium chloride, sodium chloride, or fluorinated organic acids. The electrolyte is preferably non-toxic in the event that a leak occurs *in vivo*.

[0068] Counter-electrode 18 is in electrical contact with electrolyte 14 in order to provide a return path for charge to a source 20 of potential difference between member 12 and electrolyte 14. Counter-electrode 18 may be any electrical conductor, for example, another conducting polymer, a conducting polymer gel, or a metal such as gold. In order to activate actuator 10, a current is passed between active member 12 and counter-electrode 18, inducing contraction or expansion of member 12. Additionally, the actuator preferably has a flexible barrier layer for separating the electrolyte from an ambient environment.

[0069] Additional information regarding the construction of actuators, their design considerations, and the materials and components that may be employed therein, can be found, for example, in U.S. Patent No. 6,249,076, assigned to Massachusetts Institute of Technology, and in Proceedings of the SPIE, Vol. 4329 (2001) entitled "Smart Structures and Materials 2001: Electroactive Polymer and Actuator Devices (see, in particular, Madden et al, "Polypyrrole actuators: modeling and performance," at pp. 72-83), both of which are hereby incorporated by reference in their entirety.

[0070] Referring to Fig. 2A, an artificial sphincter cuff 100 is illustrated in accordance with one embodiment of the present invention. The artificial sphincter cuff 100 is adapted to be wrapper around a body lumen of interest, whereupon opposing ends of the artificial sphincter cuff are secured to one another. For example, in the embodiment of the invention illustrated in Fig. 2A, the artificial sphincter cuff is equipped with holes 102 (one numbered), which allow the device to be laced in place after wrapping around a lumen of interest, for example, using suture materials.

[0075] Of course, the active members 112 can be disposed on the substrate layer 110 in any number of configurations. For example, Fig. 3B illustrates a substrate 110 that has twelve diagonal active members 112 (one numbered) disposed upon it. This configuration results contraction forces having both vertical and horizontal vector components. Fig. 3C, on the other hand, illustrates seven active members 112 (one numbered) disposed on a substrate 110. In contrast to the configurations of Figs. 3A and 3B, however, the configuration illustrated in Fig. 3C results in contraction forces having a predominantly horizontal component.

[0076] Multiple layers of actively members 112 are also possible. For example, it is possible to combine a substrate layer 110 having horizontal active members 112 like that illustrated in Fig. 3C with a substrate layer 110 having vertical active members 112 like that illustrated in Fig. 3D, to provide a contraction force having both horizontal and vertical vectors.

[0077] As discussed above, beneficial materials for use in the construction of the active members 112 include electroactive polymer materials known in the art such as polyaniline, polypyrrole, and polyacetylene.

[0078] To allow operation of the active members 112, the active members 112 and the counter-electrode 118 are typically connected to the appropriate terminals of a voltage source using any appropriate electrical connector. In other embodiments, however, it may be desirable to connect only one of (a) the active members 112 or (b) the counter-electrode to the power source, while grounding the other of (a) and (b), using the body as a ground, for example.

[0079] Where the active members are controlled as a group, a simple switch can be used as a control unit to activate them. Where individual control is desired, on the other hand, each active member is preferably in communication with, and is individually controllable by, a computer or other suitable control unit. This allows the control unit to individually perform operations on each active member for the purpose of effecting changes to the configuration of the overall device, for example, as a function of time.

[0080] The active members may be in direct communication with the control unit by means of individual dedicated circuits linking each of these elements to the control unit. Alternatively, it is also possible to place each active member is in

power within the device, particularly where a highly conductive substrate material such as a metal foil is used as the substrate layer 110.

[0084] Although not illustrated in Fig. 2B, it may be desirable to provide a barrier layer between the substrate layer 110 and the outside environment, particularly where a conductive substrate layer 110 is used.

[0085] Polymeric materials preferred for use in the construction of the substrate layer 110 are biocompatible, biostable polymers (i.e., polymers that do not substantially degrade *in vivo*). Preferred biocompatible, biostable polymers include numerous thermoplastic and elastomeric polymeric materials that are known in the art. Polyolefins such as metallocene catalyzed polyethylenes, polypropylenes, and polybutylenes and copolymers thereof; ethylenic polymers such as polystyrene; ethylenic copolymers such as ethylene vinyl acetate (EVA), ethylene-methacrylic acid and ethylene-acrylic acid copolymers where some of the acid groups have been neutralized with either zinc or sodium ions (commonly known as ionomers); polyacetals; chloropolymers such as polyvinylchloride (PVC); fluoropolymers such as polytetrafluoroethylene (PTFE); polyesters such as polyethylene terephthalate (PET); polyester-ethers; polysulfones; polyamides such as nylon 6 and nylon 6,6; polyamide ethers; polyethers; elastomers such as elastomeric polyurethanes and polyurethane copolymers; silicones; polycarbonates; and mixtures and block or random copolymers of any of the foregoing are non-limiting examples of biostable biocompatible polymers useful for manufacturing the medical devices of the present invention.

[0086] Among the more preferred biostable polymeric materials are polyolefins, polyolefin-polyvinylaromatic copolymers including polystyrene-polyisobutylene copolymers (more preferably copolymers of polyisobutylene with polystyrene or polymethylstyrene, even more preferably polystyrene-polyisobutylene-polystyrene triblock copolymers described, for example, in U.S. Patent No. 5,741,331, U.S. Patent No. 4,946,899 and U.S. Serial No. 09/734,639, each of which is hereby incorporated by reference in its entirety) and butadiene-styrene copolymers, ethylenic copolymers including ethylene vinyl acetate copolymers (EVA) and copolymers of ethylene with acrylic acid or methacrylic acid; elastomeric polyurethanes and polyurethane

the appropriate terminal of a power source. On the other hand, in the absence of an insulating barrier layer 120, the counter-electrode layer 118 will be in contact with the body, which may be desirable where the body serves as an electrical ground for the device.

[0092] Preferred materials for the barrier layer 120 include the polymeric materials discussed above in connection with the substrate layer 110.

[0093] The specific cross-section illustrated in Fig. 2B also includes a flexible mesh layer 122, which can be composed of any number of biocompatible materials, including metallic or polymeric materials. The mesh layer 122 can serve several purposes. For example, in the event the mesh layer is placed adjacent tissue in the patient, fibrotic tissue in-growth can occur, further securing the device to the tissue.

[0094] The mesh layer 122 can also act as a structural element that provides a mechanical bias to the device 100. For example, an elastic mesh layer 122 can be disposed such that it biases the artificial sphincter to its extended state.

[0095] More generally, in some embodiments, the devices of the present invention are provided with a restoring force that biases the device toward a preselected configuration. In such embodiments, the active members are used to move the device away from this preselected configuration. For example, the device can include one or more structural elements that are sufficiently elastic to restore the device to an expanded configuration upon relaxation of the active members within the device. The device can be changed into a contracted configuration by simply contracting the active members disposed within the device. The mesh layer 122 constitutes but one way in which this restoring force may be provided.

[0096] The various layers of the device of Fig. 2A are preferably registered with one another and the layers are bonded together to form a unitary mass using a number of suitable known techniques. Such techniques may include, for example, lamination, spot welding, the use of an adhesive layer or a tie layer, and so forth.

[0097] Although not illustrated, the edges of the structure of Fig. 2B are preferably sealed, for example, to avoid release of electrolyte and to avoid electrical edge effects. This can be accomplished in a number of ways. As a specific example, this objective can be achieved by extending the substrate layer 110 (if insulating) and the barrier layer 120 beyond the other components (i.e., beyond the active members 112,

section of the device is provided by including a substrate 110 of variable cross-section. Other layers, or combinations of layers, can be used to achieve this effect. However, the active members 112, which are generally on the order of about 30 microns in thickness, are less useful for this purpose as they typically do not exhibit substantial changes in thickness.

[0103] The devices of the present invention are adapted to be surgically inserted into the body of a patient. For example, the devices of the invention can be used as artificial urethral sphincter cuffs to remedy urinary incontinence by providing a substitute for defective urethral sphincter muscles.

[0104] Referring now to Figs. 6A and 6B, an artificial urethral sphincter in accordance with the present invention may be surgically implanted within a human torso. An artificial sphincter cuff 100 circumscribes urethra 130, which extends from the bladder 132 to the outside environment. In these embodiments, the voltage source 140 is located within the abdominal cavity, and a switch 142 is located within the scrotum in the case of a male patient or the labia in the case of a female patient, so that it may be externally manipulated by pressing it through the skin. Of course, switches that do not require the user to physically contact them, such as magnetically controlled or radio controlled switches, can also be used. The voltage source 140, switch 142 and artificial sphincter cuff 100 are electrically interconnected via cables 144.

[0105] The artificial sphincter can be implanted within the trunk using either an open technique or a laproscopic technique (an endoscopic technique is also possible) by first making an abdominal incision through the skin overlying the abdominal cavity. After the urethra 130 is exposed, the cuff 100 is wrapped around it and the ends secured to one another. The cuff 100 is wrapped, for example, around the bladder neck in most women and around the bulbous urethra in most males. This implantation procedure is analogous to prior art artificial sphincter implantation procedures, in which a cuff is placed around the urethra, a pressurized source is placed in the abdominal cavity, and a squeeze pump is placed in the scrotum or labia.

[0106] The voltage source 140 may be replaceable, for example by a surgical procedure, or rechargeable, for example, by magnetic coupling or by connecting external leads to the device.

well as those of Figs. 6A, 6B, 7A and 7B above) is preferably of a design akin to that discussed above in connection with Figs. 2A and 2B, other designs are possible. For example, referring now to Fig. 8B, an artificial lower esophageal sphincter is illustrated that, like the artificial lower esophageal sphincter of Fig. 8A, includes a cuff portion 100, which is operated by voltage source 140 and switch 142. Leads 143 and cables 144 are provided to connect respective terminals of the voltage source 140 with the counter-electrode and the active members found within the sphincter cuff 100.

**[0111]** At the core of the cuff 100 illustrated in Fig. 8B is an annular wire mesh tube 115. The wire mesh tube 115 (wire mesh structures of this type are well known, for example, in the art relating to vascular and other endoluminal stents) is preferably constructed of an elastic plastic or metal material, such as nitinol, elgiloy and/or other shape memory metal or polymer. Surrounding the wire mesh tube 115 is a group of active members 112 (one numbered), which are preferably disposed on a substrate layer 110 as discussed above in connection with Fig. 2B. Although not illustrated, an electrolyte-containing layer is typically disposed between the active members 112 and a counter-electrode. Finally, a barrier layer 120 is provided over the entire assembly.

**[0112]** When the active members 112 are contracted, the diameter of the tubular cross-section of the wire mesh tube 115 is reduced, increasing the overall length of the tube (much like the children's toy known as the "Chinese finger trap" lengthens as it tightens its grasp on one's fingers). As a result, the cuff portion 100 is loosened, opening the lumen that it surrounds (i.e., the lower esophagus). Conversely, when the active members are relaxed, the tubular cross-section of the wire mesh tube 115 increases (due to its inherent elasticity), shortening the overall length of the tube 115 and thereby constricting the lumen.

**[0113]** Structures other than the above wire mesh tube 115 can also be used, including compliant tubular ring structures with variable stent-like cell geometry or with a plurality of individual modules configured radially or spirally, to enable opening and closing functions that are analogous to a camera aperture. Double annular structures can also be used, for example, where the inside annulus is provided with the electroactive polymer actuators and the outer annulus is static.

**[0114]** In simpler embodiments, such at those discussed immediately above, the

signals from the sensors using an appropriate algorithm. Once it is determined by the computer that appropriate conditions are present, a control signal is sent to the artificial lower esophageal sphincter to open it.

[0119] Even with the use of sensors, however, it may be preferred to have a manual backup switch that is accessible to the user in the event of system failure. A backup power source, for example one outside the body, may also be desired in the event that the internal power source 140 fails. The backup power source can be connected using the same electrical circuitry that is discussed above in connection with recharging the internal power source 140.

[0120] Referring now to Fig. 8C, a lower esophageal sphincter system is illustrated that includes the artificial sphincter cuff 100 and the voltage source 140 illustrated in Fig. 8A. In addition, sensors 145, 146 are provided on the esophagus and on the stomach, respectively, which provide input to a signal analysis and control unit 148, preferably a computer. Components that may be provided within the signal analysis and control unit 148 include signal converters (e.g., analog-to-digital and digital-to-analog converters), signal amplifiers, and or more microprocessors.

[0121] As an example, the signals from the sensors 145, 146 can be amplified and converted into digital signals, as required. Subsequently, the signals from the sensors 145, 146 are analyzed by the microprocessor using a suitable algorithm. Upon receipt of an appropriate signal(s) from the sensors 145, 146, an output signal is sent to the cuff portion 100 of the artificial sphincter, using any required signal converters and/or amplifiers, relaxing the cuff portion 100.

[0122] Other embodiments of the invention relate to artificial muscles patches, which can, among other things, make up for loss of muscle function within compromised tissue. Referring now to Fig. 9A, a heart 150 is illustrated having affixed thereto an artificial muscle patch 101. The patch 101 illustrated occupies an area generally corresponding to the left ventricle of the heart.

[0123] The internal active members 112 (one numbered) are illustrated with hidden lines in Fig. 9A. As with the above artificial sphincter devices, the active members 112 within the artificial muscle patch of Fig. 9A can be disposed within the patch in a number of ways, including the disposition of arrays of active members upon one or more sheets of substrate material within the device.

present invention can be either controlled as a group or individually controlled. Where controlled as a group, the active members 112 can simply be placed in a mode where they are in a constantly contracted state, allowing the patch to act as a simple cardiac constraint device in this instance. A simple switch is all that is required for electrical control of the active members in this case.

[0131] The active members 112 can also be controlled as a group in a pulsed fashion to approximate the function of heart muscles. In this instance, the control unit will typically include a pacing unit, which can be used to both pace the heart muscles and the active members of the artificial muscle patch. Pacing of the artificial muscle patch 101 can, for example, assist heart contraction during systole.

[0132] Alternatively, a sensor (not shown) can be used to determine the natural pace of the heart. The signal from this sensor (after amplification and digitization, if required) can be fed into a computer or other logic device where it is analyzed (using, for example, an appropriate algorithm) to determine pacing of the signal that is sent to the active members 112 within the artificial muscle patch.

[0133] In other embodiments, the active members 112 are all paced in accordance with the overall heart rate, but are also actuated at slightly different times in accordance with a suitable algorithm. In this case, as previously discussed, individual cables can be provided to individually activate the active members 112 or an appropriate multiplexing scheme can be used.

[0134] As above, the extent of contraction of the active members will typically be determined by the voltage of the power supply in combination with the intrinsic, position-dependent electrical properties of the active member. However, if desired, the artificial muscle patch may be provided with a plurality of sensors, such as strain gauges, to provide electronic feedback concerning the orientation of the device.

[0135] Although the present invention has been described with respect to several exemplary embodiments, there are many other variations of the above-described embodiments that will be apparent to those skilled in the art, even where elements have not explicitly been designated as exemplary. It is understood that these modifications are within the teaching of the present invention, which is to be limited only by the claims appended hereto.

10. The artificial sphincter of claim 3, wherein said substrate layer is a conductive layer.

11. The artificial sphincter of claim 1, wherein opposing ends of said cuff are provided with fasteners for securing said cuff around said body lumen.

12. The artificial sphincter of claim 1, wherein said control unit comprises a power source and a switch.

13. The artificial sphincter of claim 1, wherein said cuff is adapted for placement around the urethra.

14. The artificial sphincter of claim 1, wherein said cuff is adapted for placement around the anal canal.

15. The artificial sphincter of claim 1, wherein said cuff is adapted for placement around the lower esophagus.

16. The artificial sphincter of claim 15, further comprising a sensing system for detecting when food or beverage enters said esophagus.

17. The artificial sphincter of claim 15, further comprising a sensing system for detecting when the stomach is attempting to regurgitate its contents.

18. The artificial sphincter of claim 1, wherein said electroactive polymer actuators comprise an electroactive polymer selected from the group consisting of polyaniline, polypyrrole, and polyacetylene.

19. The artificial sphincter of claim 18, wherein said electroactive polymer is polypyrrole.

a control unit electrically controlling said one or more electroactive polymer actuators to expand or contract said artificial muscle patch, wherein said patch is adapted to be implanted adjacent a patient's heart.

30. The artificial muscle patch of claim 29, wherein said one or more electroactive polymer actuators comprise (a) one or more active members, (b) a counter-electrode and (c) an electrolyte disposed between said active members and said counter-electrode.

31. The artificial muscle patch of claim 30, wherein said one or more active members are disposed on at least one substrate layer.

32. The artificial muscle patch of claim 31, which further comprises at least one barrier layer.

33. The artificial muscle patch of claim32, further comprising an exterior mesh layer.

34. The artificial muscle patch of claim 31, wherein said one or more active members are provided in a nonlinear configuration.

35. The artificial muscle patch of claim 31, wherein at least two of said substrate layers are provided.

36. The artificial muscle patch of claim 31, wherein said substrate layer is an insulating layer.

37. The artificial muscle patch of claim 36, wherein conductive lines are provided on said substrate layer to allow electrical communication between said one or more active members and said power source.

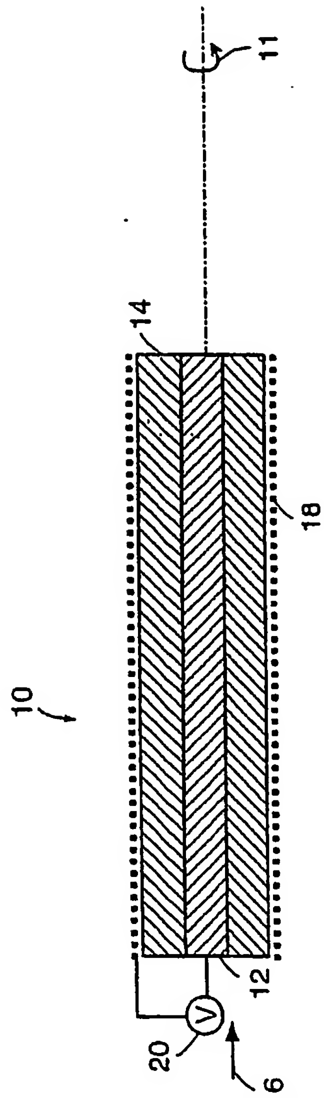



FIG. 1

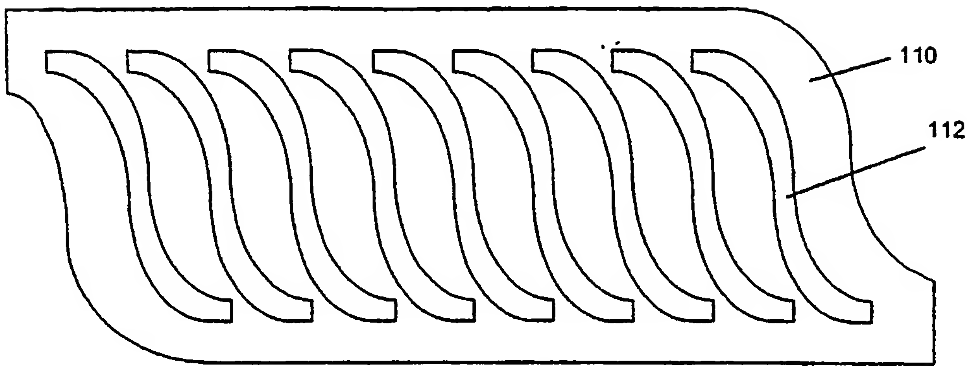



Fig. 3A

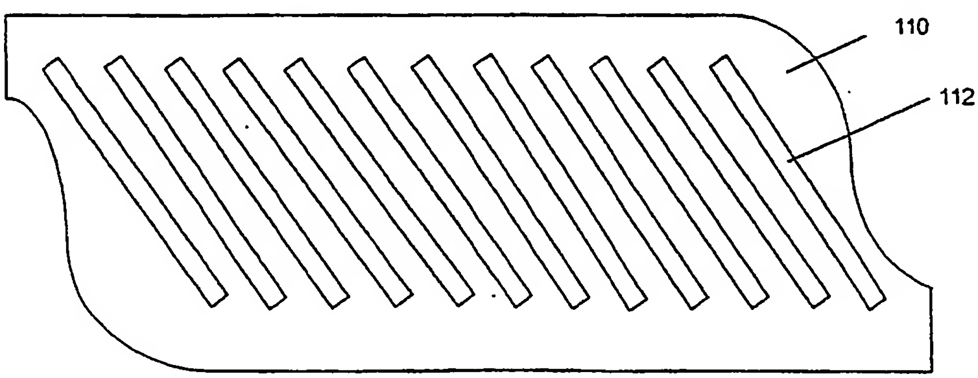



Fig. 3B

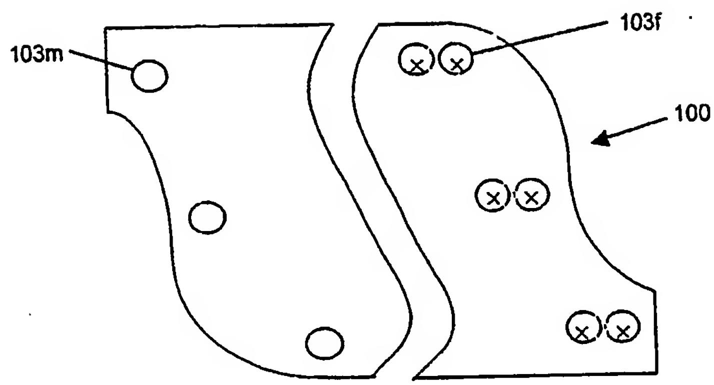



Fig. 4

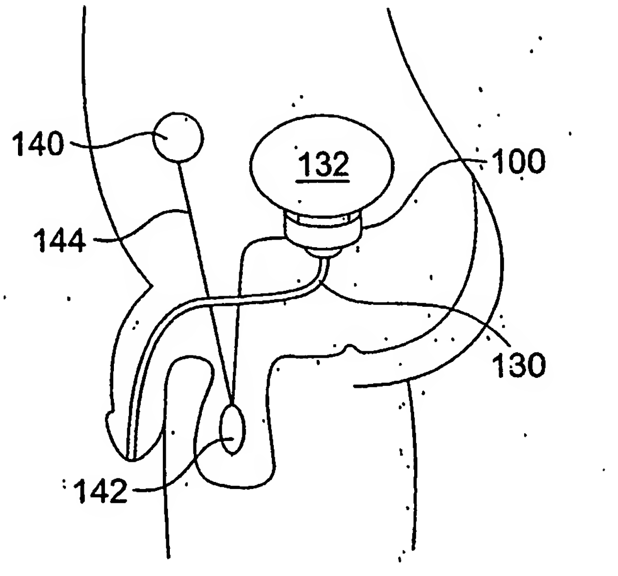



FIG. 6A

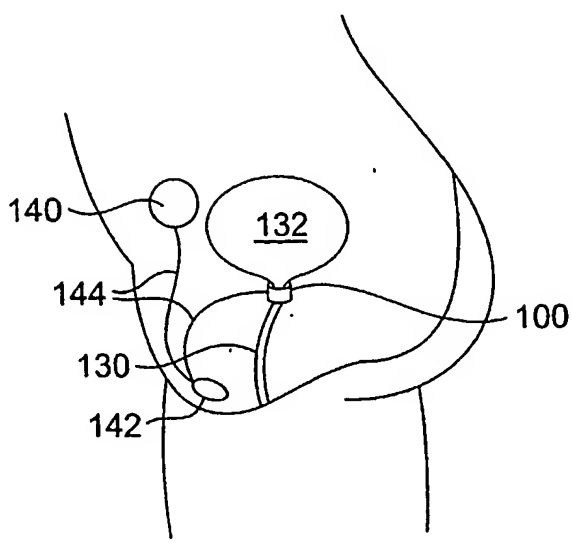



FIG. 6B

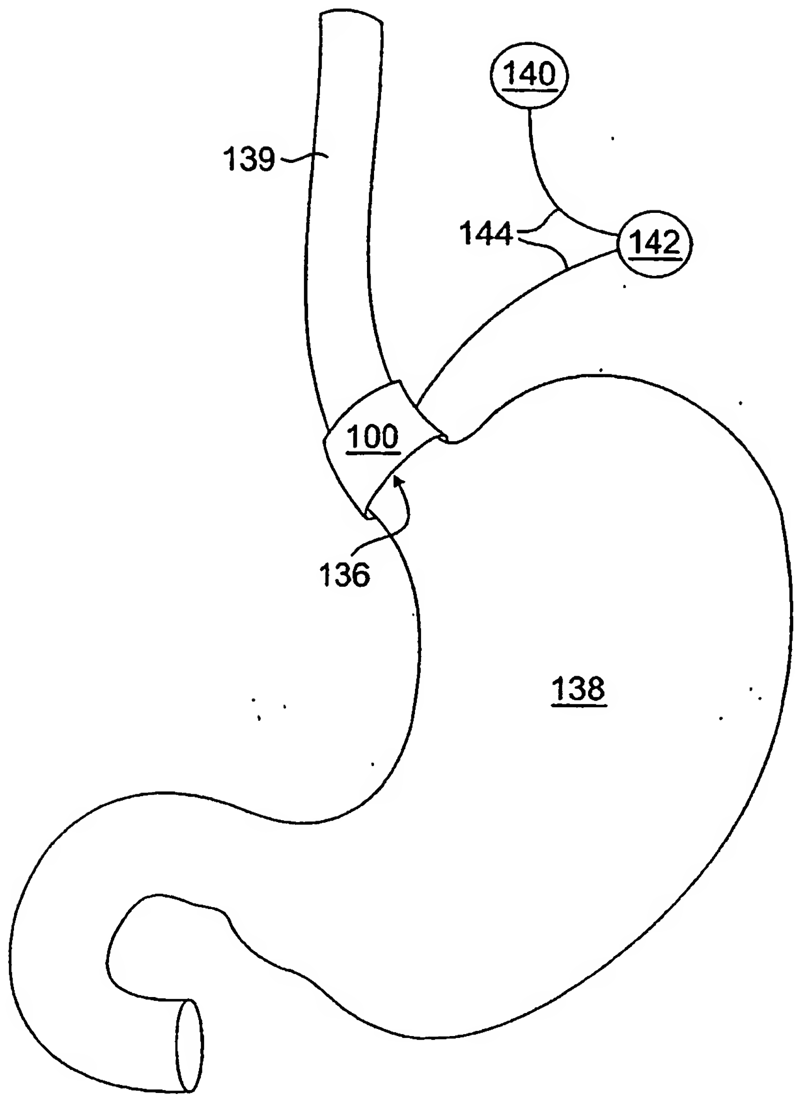



FIG. 8A

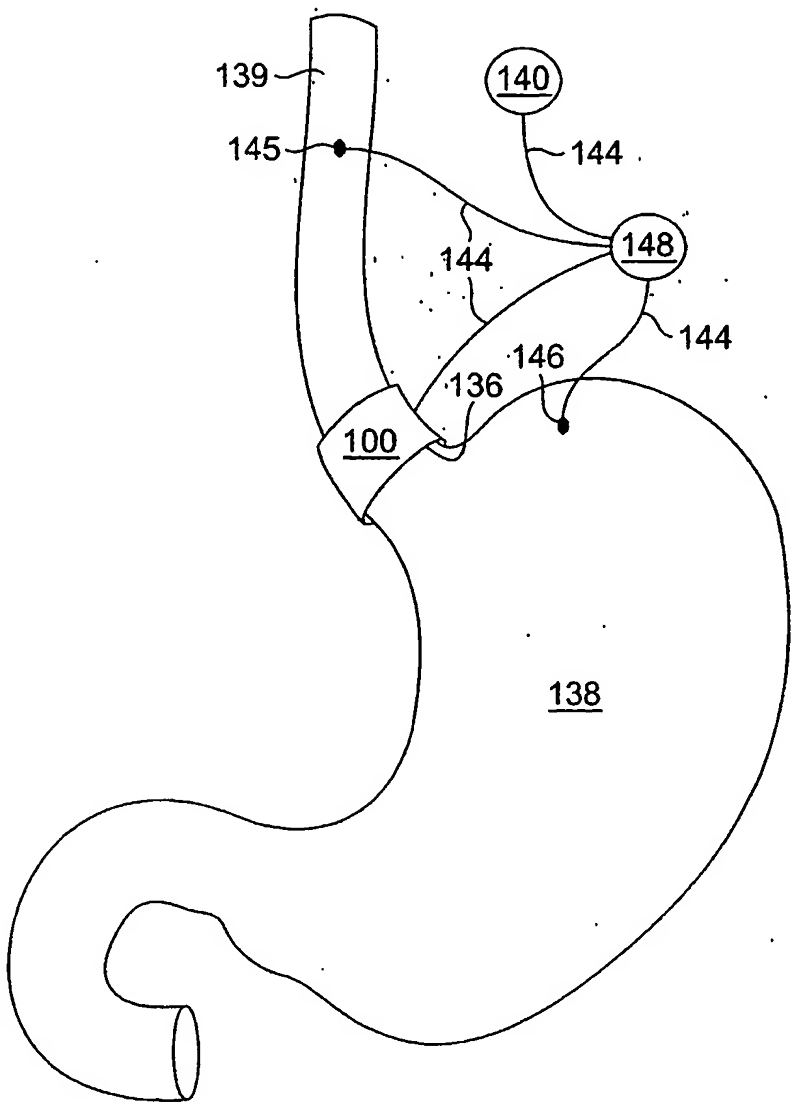



FIG. 8C

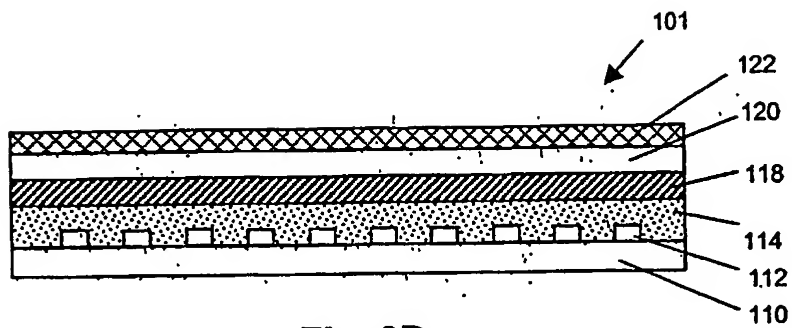



Fig. 9B

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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(10) International Publication Number
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(21) International Application Number: PCT/US2003/014624

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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, Mn 55311 (US).

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(74) Agents: BONHAM, David, B. et al.; Mayer Fortkort & Williams, PC, 2nd Floor, 251 North Avenue West, Westfield, NJ 07090 (US).

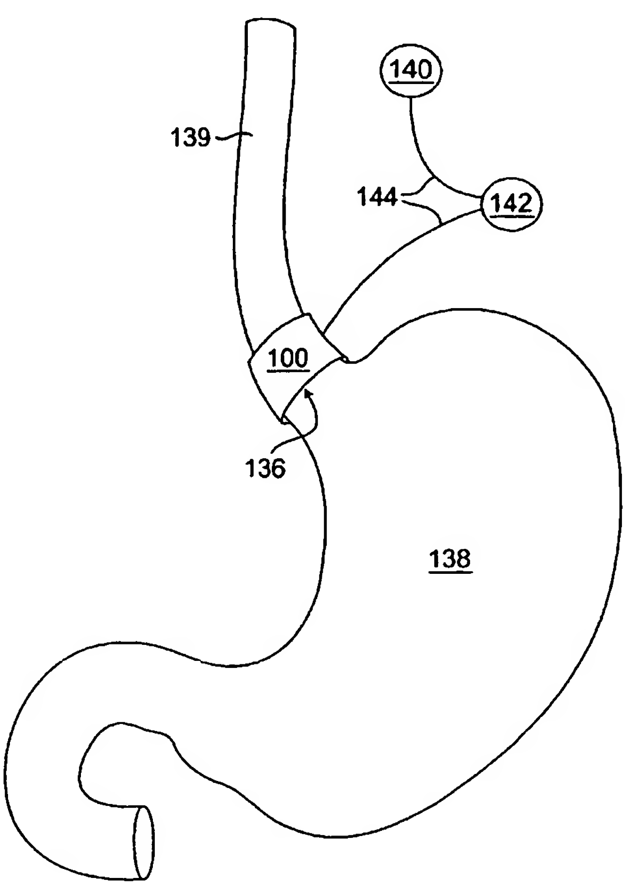
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report*

*[Continued on next page]*

(54) Title: ELECTROACTIVE POLYMER BASED ARTIFICIAL SPHINCTERS AND ARTIFICIAL MUSCLE PATCHES




**(57) Abstract:** Provided are artificial muscle patches, which are adapted to be implanted adjacent a patient's heart, and artificial sphincter cuffs, which are adapted to be implanted around a body lumen, such as the urethra, the anal canal, or the lower esophagus. The devices of the present invention comprise: (a) one or more electroactive polymer actuators; and (b) a control unit for electrically controlling the one or more electroactive polymer actuators to expand or contract the devices.

WO 2003/094800 A3

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/14624

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61F2/08

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F F03G A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 389 222 A (SHAHINPOOR MOHSEN)<br>14 February 1995 (1995-02-14)<br>column 4, line 38 - line 60<br>----- | 1,2 |
| A | WO 97/26039 A (SHAHINPOOR MOHSEN ;MOJARRAD MEHRAN (US); UNIV NEW MEXICO (US))<br>24 July 1997 (1997-07-24)<br>page 15, line 5 - line 15<br>page 23, lines 9-11<br>----- | 1 |
| A | US 5 250 167 A (ADOLF DOUGLAS B ET AL)<br>5 October 1993 (1993-10-05)<br>abstract<br>----- | 1 |
| A | US 5 100 933 A (TANAKA TOYOICHI ET AL)<br>31 March 1992 (1992-03-31)<br>abstract<br>----- | 1 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 9 October 2003 | 24 02 2004 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Korth, C-F |

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 25-27,44

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
P[redacted]/US 03/14624

| Patent document cited in search report | | Publication date | Patent family member(s) | | | Publication date |
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| | | | JP | 2000504951 | T | 25-04-2000 |
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| | | | US | 6109852 | A | 29-08-2000 |
| | | | US | 2002039620 | A1 | 04-04-2002 |
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